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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,556	10/15/2001	Barry J. Marshall	BAL-99B(16843B)	1968
7590	10/04/2004		EXAMINER	
Timothy A. Cassidy Dority & Manning, Attorney at Law, P.A. P.O. Box 1449 Greenville, SC 29602			WITZ, JEAN C	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/977,556		MARSHALL ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Jean C. Witz		1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5-7, 15-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0369292 A1 to Rothgang et al.

Rothgang, in a Diagnostic Metering Unit for Urease Determination, teaches at page 5 of the English translation that the composition of urea of urea may be provided as a powder. On page 7, the indicator may be found in a separate container or included in the urea powder, and phenol red is identified as a specific indicator. Recitation of the phrase "for sequential contact with a sample" in claim 1 is deemed a recitation of intended use that does not provide a limitation to an old composition or in this case, system. Since urea is customarily available as a powder, absent objective evidence to the contrary, the recitation of particle size of less than about 0.1 mm in claim 6 and 16 is deemed inherent in the disclosure of powdered urea in the patent document. Therefore, the reference is deemed to anticipate the cited claims.

3. Claims 1, 6-10, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by either of U.S. Patent 4,585,623 to Chandler or U.S. Patent 4,690,801 to Anderson.

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U.S. Patent 4,585,623 to Chandler teaches at col. 4, beginning at line 54, that an assay system contains urea in a powdered and dry state and an indicator in a separate container. Broadest reasonable interpretation of the term "well" includes a receptacle, container or reservoir. Recitation of the phrase "for sequential contact with a sample" in claim 1 is deemed a recitation of intended use that does not provide a limitation to an old composition or in this case, system. Since urea is customarily available as a powder, absent objective evidence to the contrary, the recitation of particle size of less than about 0.1 mm in claim 6 and 16 is deemed inherent in the disclosure of powdered urea in the patent document. In claim 14, broadest reasonable interpretation of the term "film" is deemed to include a thin sheet of any material including the coverings of the containers containing the urea and the indicator recited in the patent. Therefore, the reference is deemed to anticipate the cited claims.

U.S. Patent 4,690,801 to Anderson teaches at col. 4, beginning at line 13, that an assay system contains urea in a powdered and dry state and an indicator in a separate container. Broadest reasonable interpretation of the term "well" includes a receptacle, container or reservoir. Recitation of the phrase "for sequential contact with a sample" in claim 1 is deemed a recitation of intended use that does not provide a limitation to an old composition or in this case, system. Since urea is customarily available as a powder, absent objective evidence to the contrary, the recitation of particle size of less than about 0.1 mm in claim 6 and 16 is deemed inherent in the disclosure of powdered urea in the patent document. In claim 14, broadest reasonable interpretation of the term "film" is deemed to include a thin sheet of any material including the coverings of the

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containers containing the urea and the indicator recited in the patent. Therefore, the reference is deemed to anticipate the cited claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of U.S. Patent 4,585,623 to Chandler or U.S. Patent 4,690,801 to Anderson in view of Rothgang et al.

The disclosures of f U.S. Patent 4,585,623 to Chandler or U.S. Patent 4,690,801 to Anderson have been addressed supra. Both patents teach the use of an indicator that will show, by a color change, whether urease has acted upon urea to produce ammonia. The indicator indicated as non-limiting but exemplary is bromothymol blue, but does not distinctly disclose phenol red. Rothgang et al. also uses an indicator to show whether urease has acted upon urea to produce ammonia. Rothgang et al. teaches that phenol red will be appropriate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one conventional indicator for another as both are well known and conventional and appropriate for the same purpose and would provide a reasonable expectation of success and would not require an undue amount of experimentation.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 15-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26 and 28-29 of copending Application No. 09/977874. Although the conflicting claims are not identical, they are not patentably distinct from each other because the definitions of the terms "powdered urea" as defined in claim 16 and 17-18 meet the limitations of claim 26 and claims 28-29.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

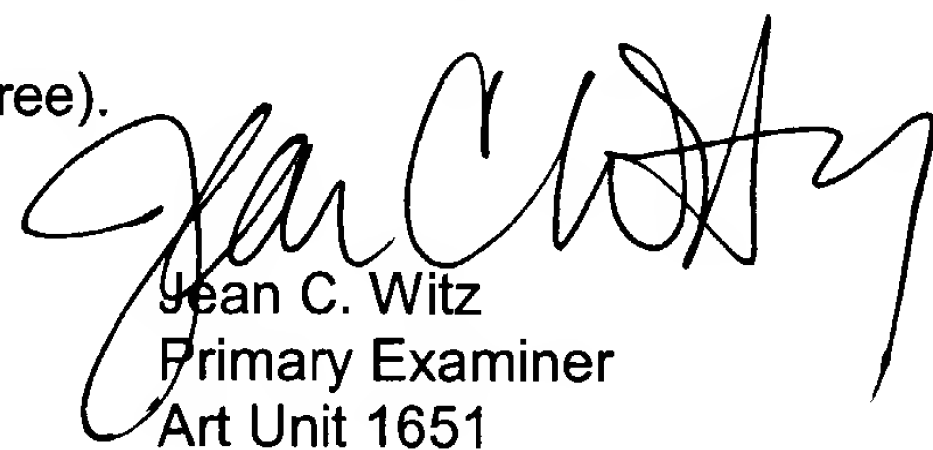
8. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/977555. Although the conflicting claims are not identical, they are not patentably distinct from each other because the system recited in the referenced claims is the same system as claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz  
Primary Examiner  
Art Unit 1651